

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

DAREN M. AMICO and DOREEN AMICO,  
his wife,

Plaintiffs,

v.

DURACAL CEMENT and INDUSTRIAL GYPSUM  
DIVISION of UNITED STATES GYPSUM  
COMPANY, a subsidiary of USG  
Corporation, ABC MANUFACTURING I-V,  
XYZ DISTRIBUTORS I-V,

Defendants.

04-4924 (WGB)

M E M O R A N D U M  
O P I N I O N

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**BASSLER, SENIOR DISTRICT JUDGE:**

Introduction

Daren M. Amico ("Amico") worked for Z-Con Construction  
Company for close to two years as a cement mixer-for four to ten

hours a day. He was exposed to a quick drying cement product known as Duracal Cement, which allegedly caused the injury.<sup>1</sup>

Defendant Gypsum Company ("Gypsum") now moves in limine to preclude the opinion of Amico's gastroenterology expert as to causation because it is inadmissible under Fed. R. Evid. 702 and 703. Gypsum also argues that without an expert opinion the case cannot go to the jury and therefore, it is entitled to summary judgment. Amico, on the other hand, contends that there is enough favorable evidence for a jury to consider even without expert medical testimony.

The Court has jurisdiction over this matter pursuant to 28 U.S.C § 1332 and venue is proper under 28 U.S.C. § 1391(a).

### **Background and Facts**

Both parties agree that with the exception of few immaterial facts the record is essentially undisputed. The following factual narrative comes largely from the deposition testimony of Amico's expert, Dr. Mark W. Babyatsky, a member of a practice group at the Mount Sinai Hospital and board certified in

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<sup>1</sup>The injury is described by Dr. Babyatsky, Amico's medical expert. "It is probable that this exposure then led to his achalasia in that the inflammation was atypical and was followed in close temporal relationship with the onset of severe and progressive dysphagia." 3/31/2000 letter of Dr. Babyatsky to Plaintiffs' counsel. According to Dr. Babyatsky, "Achalasia is a motility disorder of the esophagus that is secondary to the destruction or loss of the myenteric ganglia supplying the esophagus. The myenteric ganglia is the nervous supply of the esophagus itself." Certification of Mary S. Cook at Ex. A, Deposition of Mark Babyatsky ("Dep.") at 55:11-15.

gastroenterology. His credentials as an expert are not questioned.

Referring to case notes and progress notes, Dr. Babyatsky testified that as the result of a referral for an EGD<sup>2</sup> from Dr. Mary Jo Dimilia, Amico came to his office on March 25, 1997. Dep. at 28:3, 12-13. Dr. Dimilia informed him that Amico was helicobacter negative, a bacterial infection, which Dr. Babyatsky explained causes inflammation particularly of the stomach and peptic ulcer disease. Id. at 28:4 to 29:9.

Dr. Dimilia was prescribing Carafate—a medication for esophageal inflammation. Id. at 29:12. The results of the upper endoscopy indicated some inflammation of the stomach but no narrowing within the esophagus or any part of the upper intestinal tract. A biopsy showed that “it was negative H. Pylori” and that “there was not very much evidence of inflammation on his gastrointestinal tract.” Id. at 32:11-21.

Dr. Babyatsky’s case note entry of April 21, 1997 reflects that Amico was 31 years old at the time and worked for two and a half years at “Z/Con Mix. Cement.” Id. at 32:25 to 33:2. Amico had brought with him two prior endoscopy reports from prior physician, Dr. Pavlou,<sup>3</sup> with whom Dr. Babyatsky spoke. The

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<sup>2</sup>EGD is short for upper endoscopy, i.e., esophagogastroduodenoscopy.

<sup>3</sup>Dr. Pavlou’s notes reflect that he treated Amico from December 29, 1994 to July 8, 1996 for gastritis, dysphagia and

endoscopy report of January 1994<sup>4</sup> showed no inflammation and the one in October of 1995 in Dr. Pavlou's opinion showed "an unusual inflammation." Id. at 34:12 to 35:17, 22-24.

Amico, a former football player and weight lifter who once weighed well above 200 pounds, told Dr. Babyatsky that he began noticing his weight loss about seven months prior to his March 25, 1997 appointment. Dr. Pavlou's December 29, 1994 records showed that Amico with a height of 5'11" weighed 167 pounds.

At the April 21, 1997 office visit, Amico told Dr. Babyatsky of his exposure to Duracal Cement (prior to that time he had never heard of it) and that it was taken off the market. Id. at 43:1-14. After examining Amico, Dr. Babyatsky's impressions reflect: "31-year-old male with history of erosive gastritis, dysphagia, states post question occupational exposure to Duracal cement, question achalasia." Id. at 45:22-25. Dr. Babyatsky noted that Amico complained of difficulty with swallowing but as far as Dr. Babyatsky could recall, Amico had no complaints about his mouth or throat, and Dr. Babyatsky noticed no burns in his eyes, nose, throat or ears. Id. at 45:7-14.

As a result of the EGD, Dr. Babyatsky ruled out "peptic ulcer disease and esophageal stricture" (narrowing of the esophagus) and cancer. Id. at 47:2-14. Although Dr. Babyatsky

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difficulty swallowing. Id. at 39:5-9

<sup>4</sup>The correct date of this report is January 1995.

referred Amico to the occupational medical department at Mount Sinai for a follow-up, he apparently did not do so. Id. at 46:19 to 47:19.

Amico then underwent multiple upper GI series by Dr. Maklansky's group which reported that their findings "are characteristic of achalasia." Id. at 50:4-5. Dr. Babyatsky found this report significant because it ruled out reflux, the previous gastroenterologist's diagnosis, and confirmed Dr. Babyatsky's suspicion of achalasia. Id. at 48:19 to 50:20.

In June 1997, Dr. Babyatsky referred Amico for a Heller myotomy. Id. at 47:16.<sup>5</sup> After the Heller myotomy on July 22, 1997 and another upper GI series, Dr. Babyatsky's impressions read that the "achalasia [was] much better post myotomy. Some GERD" (Gastroesophageal reflux). Id. at 47:16-17.

After seeing Amico in October 1997, it was Dr. Babyatsky's opinion that Amico still suffered from "the initial disease of achalasia." Id. at 54:1-4; 58:8-9. Dr. Babyatsky continued to treat Amico during 1998. In February 1999 (mistakenly reported as 1997), Dr. Babyatsky received a report from Armstrong Laboratories indicating that Duracal had stuck to Amico's

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<sup>5</sup>According to Dr. Babyatsky "a Heller myotomy is a procedure done, performed exclusively for achalasia where they cut the muscle through the lower esophageal sphincter that loosens the lower esophageal sphincter and allows food and other contents coming through the mouth to pass through the lower esophageal sphincter." Id. at 51:11-17.

tympanic membrane. Id. at 63:23-64:25.

After a June 1999 visit, Dr. Babyatsky was concerned because Amico "still had achalasia with dysphagia" three years after Amico had a second myotomy to dilate his esophagus-called a Maloney dilation. Id. at 67:1-25; 58:12-14. In Amico's last visit to Dr. Babyatsky's in 1999 there was at last in Dr. Babyatsky's words "good news." Although Amico had dysphagia he had improved "finally gaining some weight." Id. at 69:1 to 70:17. Moreover, the pulmonary department ruled out either pulmonary embolic disease or interstitial lung disease. Id. at 77:7. Dr. Babyatsky agreed with the findings of Dr. DePalo who could not relate Amico's pulmonary symptoms to his abnormal physiology and "certainly [could] not relate them to his occupational exposure." Id. at 77:1-18.

**Dr. Babyatsky's Opinion that Duracal Was the Cause of Amico's Achalasia**

Dr. Babyatsky's medical opinion is succinctly in a two-page letter to Amico's counsel dated March 31, 2000:

In the case of Mr. Amico, where clear but atypical inflammation was demonstrated prior to the development of his achalasia and Duracal cement has been shown to result in burns of the esophagus, it is within a reasonable degree of medical certainty that Duracal led to his extremely severe esophageal motility disorder. While Mr. Amico demonstrates typical achalasia on motility studies, his course has been atypical in that Heller myotomy usually provides more relief than that received by Mr. Amico. In spite of the best treatment possible, Mr. Amico, at the present time remains symptomatic with upper dysphagia and profound weight loss. Under AMA guidelines, Mr. Amico is totally

disabled as a result of his condition.

**The Criteria for Admissibility of Dr.  
Babyatsky's Opinion Testimony**

The Federal Rules of Evidence provides the rule—Rule 702<sup>6</sup>—and Daubert/Paoli provide the application of that rule. In assessing whether expert testimony is based on reliable and scientifically valid methodology that corresponds (“fits”) to the facts the Supreme Court listed four guideposts (not required factors) for the District to consider: (1) whether the methodology can and has been tested; (2) whether the technique has been subjected to peer review and publication; (3) the known or potential rate of error of the methodology; and (4) whether the technique has been generally accepted in the proper scientific community. Daubert, 509 U.S. at 593-94.

In further assisting the trial court in performing its role as gatekeeper and reinforcing the Supreme Court’s admonition that this role is a flexible one, the Third Circuit in Paoli identified the following factors: (1) “the existence and maintenance of the standards controlling the technique’s operation”; (2) “the relationship of the technique to methods

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<sup>6</sup>“Rule 702 provides: ‘If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert . . . may testify thereto in the form of an opinion or otherwise.’” Daubert v. Merrell Dow Pharmaceuticals Inc., 509 U.S. 579 (1993); In re Paoli Railroad Yard PCB Litig., 35 F.3d 717 (3d Cir. 1994).

which have been established to be reliable"; and (3) "the expert witness's qualifications," and (4) "the non-judicial uses to which the method has been put." Paoli, 35 F.3d at 742 n.8.

The Third Circuit again had the opportunity to add the exposition of Rule 703 in Heller v. Shaw Ind., 167 F.3d 146 (3d Cir. 1997). Apropos to this case, Judge Becker reminded trial judges of Paoli's teaching that some flaws in a scientific method don't preclude admission if there are good grounds that the expert's conclusion should be admitted. Id. at 142. The expert's opinion must not only be based on a reliable methodology but must reliably flow from that methodology and the adjudicative facts. Id. at 152. But Judge Becker cautioned that the persuasiveness of the opinion does not have to meet either a party's burden of proof or burden of persuasion. Id. at 156. More to point here, the Court noted that Rule 703 does not require a medical expert to always rely on published studies on whether a particular product caused the particular illness.

In Heller, a homeowner had sought damages for respiratory illnesses suffered by the plaintiff after installation of an allegedly defective carpet. The Court unequivocally stated: "we do not believe that the lack of studies linking an alleged defective product to plaintiff's illness is fatal to a plaintiff's case on causation." Id. at 159.

The reason that the lack of scholarly studies is not fatal



is that the basic method of internal medicine is differential diagnosis: ordering standard library tests, physically examining the patient, taking medical histories and "considering alternate causes of the plaintiff's illness." Id. at 156 (quoting Donald J. Capra, *The Daubert Puzzle*, 32 Ga. L. Rev. 699, 728 (1998)). A qualified medical doctor can use this technique "to testify to a novel conclusion." Heller, 167 F.3d at 156 (citing Paoli, 3 F.3d at 759 n. 27)).

Heller also teaches that if a physician's diagnosis "is based in part on a strong temporal relationship between symptoms and exposure, [it] need not be supported by "a statistically significant correlation." Id. at 158. But while lack of studies is not a prerequisite to admissibility (as the trial court incorrectly found) it certainly is something the trial court can consider in evaluating whether there are "good grounds" for the expert's conclusions, which is a prerequisite to admissibility. Id. at 158. With these thoughts in mind we now turn to whether or not there are good grounds to admit Dr. Babyatsky's expert opinion.

**Whether Dr. Babyatsky's Expert Medical  
Opinion is Admissible**

The basis of Dr. Babyatsky's opinion has flaws and Gypsum has not missed any. As Gypsum notes in its Brief in Support of Motion to Exclude Testimony, according to Dr. Babyatsky himself the cause of achalasia is unknown: medical science does not "know

how the loss of the myenteric ganglia takes place." Dep. at 95:20-21. "We don't understand what are the factors that can actually lead to the loss of these specific cells that supply the nerves of the esophagus that lead to peristalsis." Id. at 95:21-25. "[W]e haven't gotten very far in understanding the pathophysiology of how that leads to achalasia." Id. at 96:10-15.<sup>7</sup>

If that were not enough, Dr. Babyatsky further testified at deposition that he agreed with Harrison's Principles of Internal Medicine that "primary idiopathic<sup>8</sup> achalasia accounts for most of the patients seen in the United States." The testimony of Dr. Babyatsky is clear: "the cause of achalasia, a disease with only esophageal manifestations, remains unknown." Id. at 22:22-25. Dr. Babyatsky took some umbrage at a statement from Sleisenger and Fordtran's text on gastrointestinal and liver disease that "data suggests that antibodies to myenteric neurons are present

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<sup>7</sup>For the first time, at the January 17, 2006 hearing for oral argument on Defendant's motion to exclude expert testimony and for summary judgment, Plaintiff informed the Court and Defendant that Plaintiff suffered from an "achalasia like" illness instead of achalasia. Plaintiff goes so far in its most recent submission to the Court dated March 13, 2006 to completely distinguish achalasia from the "insidious disease" that plagues Plaintiff. See Plaintiff's Letter Brief dated March 13, 2006 at 2. Because the cause of Plaintiff's disease is still unknown, whether Plaintiff has achalasia or an "achalasia like" disease or an "insidious disease," as Plaintiff now characterizes his illness, does not change the analysis of this case.

<sup>8</sup> As Dr. Babyatsky acknowledged "ideopathic means cause unknown." Dep. 116:15-16

in as many as half the patients with achalasia which raises the possibility of an autoimmune process." That data, Dr. Babyatsky commented, "doesn't indicate whether or not the antibody is environmental antigens or autoimmune." Id. at 117:1-14.

Each products liability case has a unique set of facts and medical opinions peculiar to those facts. In trying to get to the heart of the opinion it is necessary to understand the answer to the following question.

Q. Are you saying in the case of Mr. Amico that since you don't see any other cause for achalasia, you are saying that Duracal is the cause?

A. I didn't say that Duracal is the cause. I think that within a reasonable degree of medical certainty that the Duracal is related to his development of unusual, very unusual inflammation and a very unusual sequence of inflammation to achalasia.

Dep. at 117:19 to 118:5. To understand what Dr. Babyatsky means by this requires a return to an earlier part of the deposition; which for the sake of intelligibility the Court paraphrases: A doctor spots achalasia after the patient develops "a hard and tight esophageal sphincter." Id. at 90:11-15. When that happens it is hard to find any evidence of inflammation. Id. at 90:11-15. But the inflammation prior to the diagnosis could not be attributed to anything like GERD or specific pathogens. Id. at 91:18 to 92:7.

Since Dr. Babyatsky could not account for what caused the inflammation of the esophagus he concluded that since Duracal was

taken off the market it is "definitely a possibility as to the cause of inflammation and subsequent development of achalasia because that sequence is so particularly unusual." Id. at 92:8-9. In other words, since Dr. Babyatsky could not account for the cause of the inflammation, the cause must be Duracal and since the inflammation must have caused the achalasia it is "within a reasonable degree of medical certainty that Duracal led to [Amico's] extremely severe esophageal motility disorder. Id. at 90:1 to 91:15; 3/31/2000 Letter of Dr. Babyatsky to Plaintiffs' counsel.

One of the problems with this is that Dr. Babyatsky cannot link the inflammation to achalasia. Does esophageal inflammation cause achalasia? That is the question. Dr. Babyatsky testified that he had never seen another case of achalasia where there was inflammation of the esophagus. Nor, as Dr. Babyatsky acknowledged, is there enough data to make a clear association between environmental substances and achalasia. Id. at 121:22 to 122:5. The only environmental agent identified as an agent is a protozoa, (Id. at 123:2-6) *Trypanosoma cruzi*, found in South America but not the United States. Id. at 97:16-20.

Q. Are you saying that the inflammation that he had progressed to achalasia.

A. That's possible. I can't prove that. What I am saying is that the inflammation was of an unusual degree. It then had evidence of unusual healing with hyperkeratotic plaques.

Finding two disorders inflammation of the esophagus and achalasia in the same patient is unusual but could it be coincidental? Absolutely.

Id. at 109:16 to 110:13. And more remarkably is the following colloquy:

Q: Is there something in Duracal that you believe causes inflammation of the esophagus?

A: Im not an expert on that, not to my knowledge.

Id. at 110:14-18.

Is the opinion of Dr. Babyatsky salvageable? That depends. In Heller, the expert relied on the installation of the carpet and Heller's illness. That is because this Circuit and others "have looked favorably on medical testimony that relies heavily on a temporal relationship between an illness and a causal event." 167 F.3d at 153 or 154 (citation omitted).

In Heller, the Court of Appeals had "no problem concluding that the temporal relationship between the exposure to the Shaw carpeting and the onset of Heller's illness was questionable at best and exculpatory at worst." 167 F.3d at 158 (sustaining the District Court's conclusion of an inadequate temporal relationship where Heller experienced respiratory problems almost two weeks after the installation of the carpet and had the same problems almost a week after the carpet was removed).

Like the expert in Heller, Dr. Babyatsky relied on the exposure to Duracal and the evidence of inflammation: in his words "the most important aspect of the case." Id. at 85:3-9.

It was Dr. Babyatsky's understanding that Amico had esophageal inflammation including hyperkeratotic plaques while he was working with Duracal. In his first letter report dated February 25, 1998 he wrote:

As the etiology is unknown his symptoms developed while he was working with the Duracal and he had initial active inflammation having an EGD while working with the Duracal . . . .It is my opinion that it is a possible or even a probable cause of his achalasia. [emphasis supplied].

Dep. at 84:20-24; 91:10-12.

At his deposition, Dr. Babyatsky stated "that prior to seeing [Amico] . . . at least on October 30, 1995, he had evidence of inflammation, moderate inflammation in the esophagus, including hyperkeratotic plaques." Id. at 85:3-9. The October 30, 1995 report refers to the endoscopy report of Dr. Pavlou, Amico's previous gastroenterologist. What Dr. Babyatsky seems totally unaware of is that Amico had stopped working with Duracal by March of 1994. The first EGD, the one performed by Dr. Pavlou in January 4, 1994 indicated no inflammation. Id. at 35:1-25. And with the achalasia at work, Dr. Babyatsky's EGD in April 1997 evidenced no inflammation of the esophagus. Id. at 35:10-11 ("my endoscopy showed no inflammation").

The first EGD in 1995 reflected no esophageal inflammation. The one 10 months later, some, and the one in 1997, more. Since Amico's last exposure to Duracal was in February or March of 1994 there is also no temporal relationship between Amico's exposure

to Duracal and his symptoms.

Considering the lack of any medical data supporting a nexus between esophageal inflammation and achalasia, the absence of a temporal relationship between the exposure to Duracal and presence of achalasia, the Defendant's motion to exclude Dr. Babyatsky's opinion as to the cause of Amico's achalasia<sup>9</sup> is granted.

**The Motion to Exclude the Opinion  
of Dr. Bernard Eisenstein**

Dr. Bernard Eisenstein originally saw Amico for a pulmonary evaluation. Since he is not a gastroenterologist it is difficult to see how his opinion about achalasia would be helpful. Since he had to rely on Dr. Babyatsky for information as to whether a burn of inflammation could lead to achalasia (Cook Cert. Ex. D, Deposition of Bernard Eisenstein ("Eisenstein Dep.") at 71:3-11 to 72:9-16), his opinion must also be excluded.<sup>10</sup>

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<sup>9</sup>Heller instructed that exclusion of testimony as to causation does not preclude necessarily testimony of a treating physician as to his other reliable testimony such as examination of the plaintiff, tests and diagnosis.

<sup>10</sup>Credibility is for the jury not the judge, but it is interesting that Dr. Eisenstein opined in his original letter of October 17, 1997 to Amico's counsel that "achalasia is a disease of esophageal mobility due to disease of the various nerve plexi in the esophageal muscle. The cause of the disease is unknown and is not related to his occupational exposure." 10/17/1997 Letter from Dr. Bernard Eisenstein to Jon Gelman.

**Whether Amico Can Get to a Jury Without  
An Expert Opinion as to Causation**

Amico argues that he can still prove that Duracal caused his achalasia because the testimony of Charles Byer, a gypsum employee, stated that the compounds used in manufacturing Duracal Cement will cause injury to the esophagus. Moreover, Gypsum's Material Safety Data Sheets demonstrate "causation between the present medical condition of Daren Amico with the product manufactured by the defendant . . . ." Plaintiffs' Opposition Memorandum of Law (Pls. Opp. Mem. at 19. The Material Safety Data Sheets warn:

- if inhaled, the product can be irritating and corrosive to the respiratory tract.
- if digested, the product could harden and be corrosive to the digestive tract.
- if ingested, caustic burns may occur in the mouth, esophagus or stomach.

Pls. Opp. Mem. at Ex. A-E. Dr. Babyatsky's testimony negated any signs that Amico had caustic burns to his mouth, ears, nose, throat or eyes. Dr. Babyatsky described alkali burns from what anyone saw in Amico, finding no evidence of alkali burns in the esophagus. Dep. at 123:14-16. Nor was any esophageal inflammation ever diagnosed while Amico worked with Duracal. While Duracal was found in the wax of Amico's ear, there was no evidence of any obstruction attributable to the Plaster of Paris



component of Duracal. Although Plaintiff suggested that he suffered from esophageal burns at the January 17, 2006 hearing, the testimony of Dr. Babyatsky at the March 6, 2006 Daubert hearing is telling<sup>11</sup>:

Q. There's a term used in the certification at paragraph three. You use the term "esophageal burns."

Now Dr. Babyatsky, in any of your progress notes, did you ever write the term esophageal burns.

A. No

March 6, 2006 Daubert Hearing at 55. Dr. Babyatsky further testified that alkali burns would not result in hyperkeratotic plaques, of which Plaintiff's medical tests showed evidence. Therefore, Plaintiff's delayed claims that he suffered burns in his esophagus lack credibility.

Amico inexplicably argues in his brief at p.1 that whether Amico has achalasia is irrelevant. How can it be? The disease for which Amico sought treatment, the disease for which he was being treated, the disease that is the subject of the experts' reports and the disease for which Amico seeks compensation from Gypsum is not some vague disease but is achalasia. Nothing in Byers's testimony or the Material Data Safety Sheets support a conclusion that Duracal caused esophageal inflammation and that

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<sup>11</sup>Defendant argues that it did not receive a certification dated August 3, 2005 supporting Plaintiff's opposition to Defendant's motion, which specified that Plaintiff had "esophageal burns" and "achalasia-like symptoms" until January 18, 2006, only one day after the hearing.

inflammation caused Duracal.

Without expert medical testimony there is no evidence of causation to support any of Amico's negligence/products liability claims. See Tormenia v. First Investors Realty Co., 251 F.3d 128 (3d Cir. 2000) ("New Jersey law does require expert testimony, however, in cases where lay jurors confront causation issues that are too complex to be understood without the assistance of specialized expert testimony"). A leap of faith may be appropriate in other contexts, but it is no substitute for evidence of causation in a civil case. Without it Amico's claims fail.

#### **Conclusion**

Gypsum's motion to exclude Dr. Babyatsky and Dr. Eisenstein's opinions as to causation is granted. Consequently judgment is granted to Gypsum on all of Amico's claims.

An appropriate Order accompanies this Opinion.

/s/ William G. Bassler  
WILLIAM G. BASSLER, U.S.S.D.J.

Dated: August 8, 2006